DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-703/S-065
NDA 19-675 S-031
NDA 20-251/S-016

Glaxo Group Limited d/b/a GlaxoSmithKline
Attention: Elizabeth A. Nies
Senior Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Nies:

Please refer to your supplemental new drug application dated October 27, 2004, received October 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zantac® (ranitidine hydrochloride) 150/300 mg Tablets, USP, Zantac® (ranitidine hydrochloride) Syrup, USP, and Zantac® (ranitidine hydrochloride effervescent) 25/150 EFFERdose® Tablets and 150 (ranitidine hydrochloride effervescent) Granules.

This supplemental new drug application provides for revisions to the prescribing information for the aforementioned drug products.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Giuseppe Randazzo, Consumer Safety Officer, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick

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